

Safety Data Sheet

according to regulation (EU) No. 1907/2006

Printing date: 07.12.2023

Majesthetik-Gingiva Comp. B

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1. Identification of the substance/mixture and of the company/undertaking

- 1.1. Product identifier** Majesthetik-Gingiva Comp. B
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Use of the substance/preparation Gingiva mask material
- 1.3. Details of the supplier of the safety data sheet**
Address/Manufacturer picodent Dental Produktions- und Vertriebs-GmbH
 Lüdenscheider Str. 24-26
 D-51688 Wipperfürth
 +49 2267 6580-0
 picodent@picodent.de
 www.picodent.de
 picodent Dental Produktions- und Vertriebs-GmbH
 Telefon-Nr. +49 2267 6580-0
- 1.4. Emergency contact number:**
Medical Emergency information in case of poisoning: -24 h – Phone: +49 6131 19240
 advisory service in German or English language
 Poison Information Center Mainz

2. Hazards identification

- 2.1. Classification of the substance or mixture** This product is not classified hazardous in accordance with Regulation (EC) No 1272/2008.
- 2.2. Label elements**
Labelling according to regulation (EC) No 1272/2008
Supplemental information EUH210
 Safety data sheet available on request.
- 2.3. Other hazards** No special hazards have to be mentioned.
- The product contains no PBT substances. The product contains no vPvB substances. This product does not contain a substance that has endocrine disrupting properties with respect to human. The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

3. Composition/information on ingredients

- 3.2. Mixtures**
Chemical characterization Addition-vulcanising 2-component silicone
Hazardous ingredients
- Cristobalit**
 CAS-Nr. 14464-46-1
 EINECS-Nr. 238-455-4
 Concentration ≥ 25 < 50 %
 Classification (Regulation (EC) No. 1272/2008)
 STOT RE 1 H372

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Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

CAS-Nr. 68909-20-6
 EINECS-Nr. 272-697-1
 Registration no. 01-2119379499-16
 Concentration ≥ 1 < 10 %
 Classification (Regulation (EC) No.1272/2008)
 STOT RE 2 H373

Name of set of nanoform Nanoagglomerate
 Particle size distribution d50 2,5-50 nm
 Method Transmission Electron Microscopy (TEM)

Shape and aspect ratio of particles Spheroidal

4. First aid measures

4.1. Description of first aid measures

General information

No special measures required

After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment.

After skin contact

In case of contact with skin wash off with warm water. Consult a doctor if skin irritation persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). In case of irritation consult an oculist.

After ingestion

Do not induce vomiting - aspiration hazard. Summon a doctor immediately.

Adhere to personal protective measures when giving first aid

First aider: Pay attention to self-protection!

4.2. Most important symptoms and effects, both acute and delayed

Until now no symptoms known so far.

4.3. Indication of any immediate medical attention and special treatment needed Hints for the physician / hazards

In the case of swallowing with subsequent vomiting, aspiration of the lungs can occur which can lead to chemical pneumonia or sphixiation.

5. Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Recommended: alcohol resistant foam, CO₂, powders, water spray/mist, Extinguishing measures to suit surroundings

Non suitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In case of combustion evolution of dangerous gases possible.

5.3. Advice for firefighters

Special protective equipment for fire-fighting

In case of combustion use a suitable breathing apparatus.

Other information

Fire residues and contaminated fire-fighting water must be disposed of in accordance with the local regulations.

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6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

Do not allow to enter drains or waterways.

6.3. Methods and material for containment and cleaning up

Pick up mechanically. Clean contaminated floors and objects thoroughly, observing environmental regulations.

6.4. Reference to other sections

Refer to protective measures listed in Sections 7 and 8.

7. Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Observe the usual precautions for handling chemicals. For personal protection see Section 8.

Advice on protection against fire and explosion

No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Store product in closed containers.

Hints on storage assembly

Do not store together with foodstuffs.

Further information on storage conditions

Keep container tightly closed and dry.

8. Exposure controls/personal protection

8.1. Control parameters

Other information

Contains no substances with occupational exposure limit values.

Mode of action

Systemic effects

Concentration

25 mg/kg/d

8.2. Exposure controls

General protective and hygiene measures

Observe the usual precautions for handling chemicals. Do not eat, drink or smoke during work time. Wash hands before breaks and after work. Avoid contact with eyes.

Respiratory protection

Not necessary.

Hand protection

Not necessary.

Eye protection

Not necessary.

Body protection

Clothing as usual in the chemical industry.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state

liquid, viscous

Colour

white

Odour

characteristic

Melting point

Remarks

not determined

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Freezing point

Remarks not determined

Boiling point or initial boiling point and boiling range

Value > 300 °C

Flammability

evaluation not determined

Upper and lower explosive limits

Remarks not determined

Flash point

Value > 160 °C

Method closed cup

Ignition temperature

Remarks not determined

Decomposition temperature

Remarks not determined

pH value

Remarks not determined

Viscosity

Remarks not determined

Solubility(ies)

Remarks not determined

Partition coefficient n-octanol/water (log value)

Remarks not determined

Vapour pressure

Remarks not determined

Density and/or relative density

Value 1,25 g/cm³

Temperature 20 °C

Relative vapour density

Remarks not determined

9.2. Other information

Odour threshold

Remarks not determined

Evaporation rate (ether = 1) :

Remarks not determined

Solubility in water

Remarks virtually insoluble

Explosive properties

evaluation not determined

Oxidising properties

Remarks not determined

Other information

None known

10. Stability and reactivity

10.1. Reactivity

No hazardous reactions when stored and handled according to prescribed instructions.

10.2. Chemical stability

No hazardous reactions known.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

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10.4. Conditions to avoid	No hazardous reactions known.
10.5. Incompatible materials	None known
10.6. Hazardous decomposition products	No hazardous decomposition products known.

11. Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity

Remarks Based on available data, the classification criteria are not met.

Acute oral toxicity (Components)

Silanamine, 1,1,1-Trimethyl-N-(trimethylsilyl)

Species rat
LD50 > 5000 mg/kg
Method OECD 401
Remarks Test conducted with a similar formulation.

Acute dermal toxicity

Remarks Based on available data, the classification criteria are not met.

Acute dermal toxicity (Components)

Silanamine, 1,1,1-Trimethyl-N-(trimethylsilyl)

Species rabbit
LD50 > 5000 mg/kg
Source Analogous

Acute inhalational toxicity

Remarks Based on available data, the classification criteria are not met.

Acute inhalative toxicity (Components)

Silanamine, 1,1,1-Trimethyl-N-(trimethylsilyl)

Species rat
LC50 > 5,01 mg/l
Duration of exposure 4 h
Administration/Form Dust/Mist
Source Analogous

Skin corrosion/irritation

Remarks Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Remarks Based on available data, the classification criteria are not met.

Sensitization

Remarks Based on available data, the classification criteria are not met.

Subacute, subchronic, chronic toxicity

Remarks not determined

Mutagenicity

Remarks Based on available data, the classification criteria are not met.

Reproductive toxicity

Remarks Based on available data, the classification criteria are not met.

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Carcinogenicity

Bemerkung

Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity (STOT)

Single exposure

Remarks

Based on available data, the classification criteria are not met.

Repeated exposure

Bemerkung

Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity (STOT) (Components)

Cristobalite

Repeated exposure

evaluation

Causes damage to organs through prolonged or repeated exposure
Route of exposure inhalative

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2. Information on other hazards

Endocrine disrupting properties with respect to humans

The product does not contain a substance that has endocrine disrupting properties with respect to humans.
endokrine Eigenschaften aufweist.

Other information

No toxicological data are available.

12. Ecological information

12.1. Toxicity

General information

not determined

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Species

zebra fish (Brachydanio rerio)

LC50

> 10000 mg/l

Expositionsdauer

96 h

Source

Analogous

Daphnia toxicity (Components)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Species

Daphnia magna

EC50

> 1000 mg/l

Duration of exposure

48 h

Source

Analogous

Algae toxicity (Components)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Species

Desmodesmus subspicatus

EC50

> 173 mg/l

Duration of exposure

72 h

Source

Analogous

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Bacteria toxicity (Components)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Species	activated sludge
EC50	> 2500 mg/l
Duration of exposure	3 h
Method	OECD 209
Source	Analogous

12.2. Persistence and degradability

General information

not determined

Biodegradability (Components)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Remarks	Inorganic product, cannot be eliminated from the water by biological purification processes
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12.3. Bioaccumulative potential

General information

not determined

Partition coefficient n-octanol/water (log value)

Remarks

not determined

12.4. Mobility in soil

General information

not determined

12.5. Results of PBT and vPvB assessment

General information

not determined

Results of PBT and vPvB assessment

The product contains no PBT substances
The product contains no vPvB substances

12.6. Endocrine disrupting properties

Endocrine disrupting properties with respect to the environment

The product does not contain a substance that has endocrine disrupting properties with respect to nontarget organisms.

12.7. Other adverse effects

General information

not determined

General information / ecology

Do not allow to enter soil, waterways or waste water canal. Avoid release into the atmosphere.

13. Disposal considerations

13.1. Waste treatment methods

Disposal recommendations for the product

Must not be disposed together with household garbage.
Dispose of waste according to applicable legislation.

Disposal recommendations for packaging

Packaging that cannot be cleaned should be disposed off in agreement with the regional waste disposal company.

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14. Transport information

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN-number or ID-number	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.
14.2. UN proper name	-	-	-
14.3. Transport hazard class(es)		-	-
Label			
14.4. Packing group		-	-

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture	All components are contained in the TSCA inventory or exempted.
Other information	
15.2. Chemical safety assessment	For this preparation a chemical safety assessment has not been carried out.

16. Other information

Hazard statements listed in Chapter 2/3

H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.

CLP categories listed in Chapter 2/3

STOT RE 1	Specific target organ toxicity - repeated exposure, Category 1
STOT RE 2	Specific target organ toxicity - repeated exposure, Category 2

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: ***

This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.